

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: HODGKINSON, et al.

Serial No.: Divisional of 09/424,246

Group Art Group: 1644

Filed: February 29, 2000

Examiner: EWOLDT, G.

For: PROCESSES FOR THE PRODUCTION OF IMMUNOGLOBULIN A IN MILK

**PRELIMINARY AMENDMENT**

Commissioner of Patents  
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the captioned application as follows:

**In the Abstract:**

Attached hereto is an Abstract that was inadvertently omitted from the parent case, U.S. Patent Application No.: 09/424,246, when the application was originally filed on February 29, 2000.

**In the Claims:**

Please cancel claims 1-46, without prejudice or disclaimer.

Please add the following claims:

47. (New) A pharmaceutical, cosmetic, or veterinary formulation comprising milk from a ruminant containing immunoglobulin A (IgA) produced by

- (a) actively immunizing a pregnant ruminant with an antigen by any two routes of administration selected from the group consisting of intramammary (IMM), intraperitoneal (IP), and intramuscular (IM); and
- (b) actively immunizing said ruminant with an antigen by a third administration route selected from the group consisting of intramammary (IMM), intraperitoneal (IP), and intramuscular (IM),

with the proviso that all three administration routes are different.

48. (New) The formulation of claim 47, wherein the two routes of administration in step (a) are IP and IM, and the third administration route of step (b) is IMM.

49. (New) The formulation of claim 47, wherein the two active immunizations of step (a) are effected sequentially, apart in time, or concurrently.

50. (New) The formulation of claim 49, wherein the two active immunizations of step (a) are effected concurrently.

51. (New) The formulation of claim 47, wherein the active immunizations of step (a) and step (b) are effected sequentially, apart in time, or concurrently.

52. (New) The formulation of claim 47, wherein step (a) and step (b) are repeated at least once prior to parturition.

53. (New) The formulation of claim 47, wherein step (a) is repeated twice, prior to parturition.

54. (New) The formulation of claim 53, wherein each step (a) is effected at an interval in the range of 2 to 8 weeks.

55. (New) The formulation of claim 54, wherein each step (a) is effected at an interval in the range of 2 to 4 weeks.

56. (New) The formulation of claim 52, wherein step (a) is effected 6 to 14 weeks prior to parturition, the first repeat step (a) is effected at 2 to 10 weeks prior to parturition, and the last step (a) is effected at 1 to 4 weeks prior to parturition.

57. (New) The formulation of claim 56, wherein step (a) is effected 8 to 14 weeks prior to parturition, the first repeat step (a) is effected at 4 to 8 weeks prior to parturition, and the last step (a) is effected at 1 to 4 weeks prior to parturition.

58. (New) The formulation of claim 57, wherein step (a) is effected 8 weeks prior to parturition, the first repeat step (a) is effected at 4 weeks prior to parturition, and the last step (a) is effected at 1 week prior to parturition.

59. (New) The formulation of claim 52, wherein step (b) is repeated once prior to parturition.

60. (New) The formulation of claim 52, wherein the repetitions of step (b) are effected at 1 to 6 week intervals.

61. (New) The formulation of claim 60, wherein the repetition is at 2 week intervals.

62. (New) The formulation of claim 59, wherein the first step (b) is effected 3 to 12 weeks prior to parturition, and the second step (b) is effected at 1 to 10 weeks prior to parturition.

63. (New) The formulation of claim 62, wherein the first step (b) is effected 4 to 8 weeks prior to parturition, and the second step (b) is effected at 2 to 4 weeks prior to parturition.

64. (New) The formulation of claim 63, wherein the first step (b) is effected 4 weeks prior to parturition and the second step (b) is effected at 2 weeks prior to parturition.

65. (New) The formulation of claim 47, wherein the antigen is selected from the group consisting of bacteria, yeasts, viruses, mycoplasmas, proteins, haptens, animal tissue extracts, plant tissue extracts, spermatozoa, fungi, pollens, dust, and a combination thereof.

66. (New) The formulation of claim 65, wherein the antigen is a yeast antigen.

67. (New) The formulation of claim 66, wherein the yeast is *Candida albicans*.

68. (New) The formulation of claim 65, wherein the antigen is a protein antigen.

69. (New) The formulation of claim 47, wherein the antigen is formulated as a suspension.

70. (New) The formulation of claim 47, wherein the antigen is administered together with a carrier, a diluent, a buffer, an adjuvant, or a combination thereof.

71. (New) The formulation of claim 70, wherein the antigen is administered together with an adjuvant.

72. (New) The formulation of claim 71, wherein the adjuvant is Freund's complete adjuvant (FCA), Freund's incomplete adjuvant (FIC), cholera toxin B subunit, or aluminum hydroxide.

73. (New) The formulation of claim 71, wherein the adjuvant is *Bordetella pertussis*, muramyl dipeptide, a cytokinin, or saponin

74. (New) The formulation of claim 72, wherein the adjuvant is Freund's incomplete adjuvant.

75. (New) The formulation of claim 47, wherein the antigen is administered together with an antibiotic.

76. (New) The formulation of claim 47, wherein the antigen used in each active immunization is the same or different.

77. (New) The formulation of claim 71, wherein the antigen used in each active immunization is the same.

78. (New) The formulation of claim 47, wherein the pregnant ruminant is a cow, goat, or sheep.

79. (New) The formulation of claim 78, wherein the cow is a dairy cow.

80. (New) The formulation comprising milk from a ruminant comprising IgA produced by

- (a) actively immunizing a pregnant ruminant with an antigen by any two routes of administration selected from the group consisting of intramammary (IMM), intraperitoneal (IP) and intramuscular (IM); and
- (b) actively immunizing said ruminant with an antigen by a third administration route selected from the group consisting of intramammary (IMM), intraperitoneal (IP) and intramuscular (IM);

with the proviso that all three administration routes are different and wherein a higher IgA titre is produced as compared to an IgA titre produced by conducting step (a) alone.

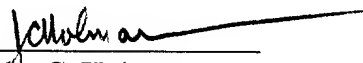
**REMARKS**

By this Preliminary Amendment, claims 1-46 are canceled without prejudice or disclaimer and new claims 47-80 are added. Support for the claims may be found in the parent specification as originally filed. No new statutory matter has been added.

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By   
John C. Holman  
Reg. No. 22,769

400 Seventh Street, N.W.  
Washington, D.C. 20004-2201  
(202) 638-6666  
Date: February 8, 2002  
Atty. Docket: 12567/P64057US2  
JCH/SKS/vjb